

Lorraine Woolgar

From: Lorraine Woolgar
Sent: Thursday, May 24, 2007 10:10 AM
To: Denise Dunn
Subject: Attached Reports

Attachments: DAKO.pdf; Recommend Immunohistochem.pdf

Hi Denise,
Heather asked me to scan the attached documents x 2 and send to you for her attention. Any questions please call me.

Have a nice day,
Lorraine



DAKO.pdf (72
KB)



Recommend
Immunohistochem.pdf

Heather
found in
Radio file
Bestie

**DAKO # Patients Selected for Retest at Mt. Sinai
HCCSJ**

| Year | Neg + Weak Pos Tests | # Deceased | # Out of Town | # Clinical Cut Off | # Patients Sent |
|----------------|----------------------|------------|---------------|--------------------|-----------------|
| 1997 | 57 (1 Patient x 2) | 1 | 24 | 0 | 31 |
| 1998 | 76 (5 Patients x 2) | 1 | 13 | 0 | 57 |
| 1999 | 62 (2 Patients x 2) | 9 | 0 | 0 | 53 |
| 2000 | 102 (2 Patients x 2) | 25 | 0 | 2 | 73 |
| 2001 | 98 (3 Patients x 2) | 21 | 1 | 7 | 66 |
| 2002 | 90 | 12 | 0 | 0 | 78 |
| 2003 | 47 | 2 | 0 | 1 | 44 |
| 2004 (Jan-Mar) | 9 (1 Patient x 2) | 0 | 0 | 0 | 8 |

Ventanna Retest

| Year | Neg + Weak Pos Tests | # Deceased | # Out of Town | # Clinical Cut Off | # Patients Sent |
|-----------------|----------------------|------------|---------------|--------------------|-----------------|
| Apr/04 – Mar/05 | 22 (2 Patients x 2) | 0 | 0 | 0 | 20 |
| Apr/05 – Jul/05 | 10 (1 Patient x 2) | 0 | 0 | 0 | 9 |

| Recommendation | Recommended By | Agree With | Current Status | Expected Completion Date |
|--|-------------------|------------|--|--------------------------|
| 47. Evaluation & appropriate use of negative controls | Trish Wegrynowski | Yes | Dr. Denic – In draft | Ongoing |
| 48. Evaluation & appropriate use of “sausage” block for positive & negative controls | Trish Wegrynowski | Yes | Dr. Denic – In draft | Ongoing |
| 49. RT’s trained to assess the quality of EXTERNAL positive & negative controls with signed documentation retained for 2 years | Trish Wegrynowski | Yes | B. Dyer, Drs Makarla, Elms, Denic – In progress | Ongoing |
| 50. Standard report headings for Eastern Health | Trish Wegrynowski | Yes | B. Dyer - Completed | Sep 06 |
| 51. The quality management policies be shared with other regions in the province | Trish Wegrynowski | Yes | Dr. Denic – In progress | Ongoing |
| 52. The QM team should be involved with quality improvement, establish quality indicators for monitoring purposes, provide a mechanism to ensure recommendations are dealt with, and create corrective action logs to investigate underlying causes. | Trish Wegrynowski | Yes | QC Dept, T. Gulliver, B. Dyer, Dr. Denic – In progress | Ongoing |

Recommendations - Immunohistochemistry Service
(Spreadsheet Dr. D. Banerjee/Trish Wegrynowski) – Updated April 26/07 by Dr. Denic, Dr. Elms, T. Gulliver, B. Dyer

| Recommendation | Recommended By | Agree With | Current Status | Expected Completion Date |
|--|---------------------------------------|------------|---|----------------------------|
| 1. Pathologists should subspecialize. | Dr. D. Banerjee | Yes | Pathologist Assigned | Completed |
| *2. One Pathologist appointed as Director of Immunohistochemistry service. Backup designate should be appointed (Trish). (Working on) | Dr. D. Banerjee/ Trish Wegrynowski | Yes | Implemented. Drs Makarla/ Elms | Completed |
| 3. Consideration to use rabbit monoclonal antibody SP1 for ER testing. | Dr. D. Banerjee | No | Being discussed | |
| *4. Dedicated Technologist for IHC. | Dr. D. Banerjee Trish Wegrynowski | Yes | 3 staff dedicated | Completed |
| 5. Pathologists attend educational and scientific conferences. (IHC) | Dr. D. Banerjee | Yes | In progress | Ongoing |
| 6. Pathologists' Assistants hired to standardize grossing procedures. | Dr. D. Banerjee Trish Wegrynowski | Yes | 3 hired to date 4 th to start in Aug 06 | Training started May 06 |
| 7. Implement Tissue-Tek X-Press and Pathologists/Technologists should redesign workflow/practices. | Dr. D. Banerjee | Yes | Partially implemented | 6-12 months |
| 8. Reinstitute Ventana ER/PR service. | Dr. D. Banerjee | Yes | Drs Makarla & Elms are investigating | Completed Feb/07 |
| *9. Enroll in external quality assurance programs. | Dr. D. Banerjee/ Trish Wegrynowski | Yes | Enrolled in CAP and UK proficiency testing | Completed |
| *10. Redesign communication structure to provide better joint technical/medical accountability. IHC Tech's report to Division Manager and Section Head depending upon issue. | Dr. D. Banerjee/ Trish Wegrynowski | Yes | Regular meetings to be scheduled | Ongoing |
| 11. Documented internal control results by Pathologists. (Linked to #25 recommendation by Trish) | Dr. D. Banerjee | Yes | Dr. Cook standardized reporting procedures | Completed |
| *12. Ensure blocks submitted for ER/PR have normal ductal epithelium. | Dr. D. Banerjee | Yes | Dr. Cook has informed Pathologists. | Completed |
| *13. Tissue processing consolidated to HSC site and SOP be available. | Trish Wegrynowski | Yes | All processing at HSC | Completed |
| *14. Pathologists need to establish a mechanism to express IHC concerns/issues. Documentation required. | Trish Wegrynowski | Yes | Dr. Cook to address in memo to all Pathologists | Completed Mar 06 |
| *15. Succession planning to be evaluated for technical and professional staff. | Trish Wegrynowski | Yes | Plan in place | 1 Year |
| 16. Procedure manual outlining the SOP's to be created for all IHC antibodies and methods including the Ventana operator's manual. | Trish Wegrynowski | Yes | In progress | Ongoing |
| *17. Antibody data specification sheets be available for all antibodies in use including lot #, clone, expiry date, etc. | Trish Wegrynowski | Yes | In progress | Completed |
| *18. Routine equipment maintenance performed and documented as per company protocols. | Trish Wegrynowski | Yes | Completed | Ongoing |

| Recommendation | Recommended By | Agree With | Current Status | Expected Completion Date |
|--|-------------------|------------|--|-------------------------------|
| 19. Documented evaluation of IHC antibodies to ensure sensitivity and specificity of results. | Trish Wegrynowski | Yes | In progress | Ongoing |
| *20. Evidence of training/competency of technical staff trained on Ventana system. | Trish Wegrynowski | Yes | Completed | |
| *21. Retired procedures/antibodies information must be retained for 2 years. | Trish Wegrynowski | Yes | In progress | Ongoing |
| *22. All technical/professional issues, concerns and corrective actions must be documented. | Trish Wegrynowski | Yes | Completed | Completed |
| 23. Implement Her-2 testing on the automated Ventana system. | Trish Wegrynowski | Yes | In progress | TBA |
| 24. IHC Technologist to be trained to assess the quality and specificity of staining for IHC daily controls. | Trish Wegrynowski | Yes | In progress | Ongoing |
| 25. Standard report headings for both Pathology sites including predictive/prognostic information on specimen processing, antibody clone, and scoring method used. | Trish Wegrynowski | Yes | Dr. Cook – In progress | Completed |
| *26. Internet availability for IHC workbench and purchase IHC textbooks as needed. | Trish Wegrynowski | Yes | Completed | |
| *27. Funding available for 1 IHC Technologist to attend the annual NSH convention. | Trish Wegrynowski | Yes | Approved (Ventana) | Completed |
| *28. Relocate the automated special stainer from the IHC Lab. | Trish Wegrynowski | Yes | Equipment installed | Completed |
| 29. Laboratory to send out up to 10 cases per month for correlation of results. | Dr. D. Cook | Yes | Upon retesting/breast group review | Ongoing |
| *30. Send technologists to Mt. Sinai and Jewish General. | Internal | Yes | Completed | Feb 06 |
| 31. SOP's for accessioning, grossing, & fixation | Trish Wegrynowski | Yes | B. Dyer, Drs Morris-Larkin & Carter working on | Sep 06 – Mar 08 |
| 32. SOP's and performance evaluation of PA's documented | Trish Wegrynowski | Yes | Dr. Morris-Larkin, B. Dyer | Mar 08 |
| 33. Refrigerators for OR's | Trish Wegrynowski | Yes | Received (SCM not done) | Jul 06 |
| 34. Document courier service times | Trish Wegrynowski | Yes | Completed | |
| 35. SOP's for tissue processor, embedding | Trish Wegrynowski | Yes | Completed | Sep 06 |
| 36. Procedures for handling of suboptimal specimens | Trish Wegrynowski | Yes | B. Dyer, Dr. Denic In progress | Sep 07 |
| 37. SOP's for IHC in compliance with Clinical & Laboratory Standards Institute | Trish Wegrynowski | Yes | Latest version purchased CD/Rom | Working on - Accreditation |
| 38. Compilation of antibody specification sheets | Trish Wegrynowski | Yes | Completed | Completed |
| 39. Microscope maintenance & documentation | Trish Wegrynowski | Yes | Completed | Completed |
| 40. Pipette accuracy & calibration documentation | Trish Wegrynowski | Yes | In progress | Ongoing |
| 41. Thermometers placed in all temperature controlled instruments | Trish Wegrynowski | Yes | Completed | |
| 42. External alarm system for antibody refrigerator | Trish Wegrynowski | Yes | Completed | |
| 43. Documentation for all pH dependent reagents/meter | Trish Wegrynowski | Yes | Completed | Completed |
| 44. Equipment/instrument selection criteria | Trish Wegrynowski | Yes | Completed | Completed |
| 45. Corrective action log | Trish Wegrynowski | Yes | B. Dyer, Dr. Denic Completed | Completed |
| 46. Establish protocol for false positive staining | Trish Wegrynowski | Yes | In progress - Draft | Ongoing |

| ER/PR Tests/Statistics | DAKO | | | | | | | | | Ventanna | | |
|--|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|------------------|---------------|-------------------|----------------------|-------------------|
| | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | Total Dako | Apr/04- Mar/05 | Apr/05- Jul 31/05 | Total Ventanna |
| Total Tests Performed | 136 | 147 | 360 | 370 | 374 | 344 | 373 | 109 | 2213 | 381 | 114 | 495 |
| # of Tests out of town | Included above | Included above | 202 No results | 162 No results | 150 No results | 155 No results | 171 No results | 42 No results | 882 | 242 No results | 55 No results | 297 |
| # HCCSJ Tests (with results) | 136 | 147 | 158 | 208 | 224 | 189 | 202 | 67 | 1331 | 139 | 59 | 198 |
| # Tests Strong Positive | 80 | 71 | 96 | 106 | 126 | 99 | 155 | 58 | 791 | 117 | 50 | 167 |
| Percentage | 59% | 49% | 61% | 51% | 56% | 52% | 76% | 86% | 59% | 84% | 84% | 84% |
| # Tests Weak Positive (30% or less 1997-2000) | *20 (14%) | 39 (26%) | 24 (15%) | 35 (17%) | - | - | - | - | 219 | - | - | 3 |
| (10% or less 2001-2004) | - | - | - | - | 47 (21%) | 34 (18%) | 18 (9%) | 2 (3%) | | 2 (1%) | 1 (2%) | 2% |
| # Tests Neg/Neg | 37 | 37 | 38 | 67 | 51 | 56 | 29 | 7 | 322 | 20 | 8 | 28 |
| Percentage | 27% | 25% | 24% | 32% | 23% | 30% | 15% | 10% | | 14% | 14% | 14% |
| # Tests Reported with Positive Staining (Strong + Weak) | 99 | 110 | 120 | 141 | 173 | 133 | 173 | 60 | 1009 | 119 | 51 | 170 |
| Percentage | 73% | 75% | 76% | 68% | 77% | 70% | 85% | 89% | 75.8% | 86% | 86% | 86% |
| # Tests Reported Neg (No staining)/Percentage | 37 | 37 | 38 | 67 | 51 | 56 | 29 | 7 | 322 | 20 | 8 | 28 |
| | 27% | 25% | 24% | 32% | 23% | 30% | 15% | 10% | 24.2% | 14% | 14% | 14% |

Summary

Total Tests = 2,708 (Dako + Ventanna)

Total with Results = 1,529

Total Positive Reported = 1,179 (77%)

Total Neg/Neg = 350 (23%)

* 1 Patient from James Paton added onto patient list in 1997